CHAPTER 4

THE NELAC ON-SITE ASSESSMENT PROCESS

This Chapter presents and discusses those aspects of the NELAC standards that specify requirements for the on-site assessment process, including:

- ➢ Qualifications and training for on-site assessment personnel;
- ➢ The types and frequency of on-site assessments, including circumstances in which non-routine on-site assessments should be conducted;
- ➢ Preassessment activities to be conducted by assessors prior to an on-site assessment;
- ➢ On-site assessment procedures;
- ➢ Reporting results of on-site assessments; and,
- ➢ Follow-up and closure activities for on-site assessments.

As stated in the NELAC standards, the principal purpose of these requirements is to ensure the consistency and quality of on-site assessments, as necessary to foster reciprocity among accrediting authorities and to encourage confidence in NELAC accreditations among the user community.

4.1 Qualifications and Training of On-Site Assessment Personnel

All NELAC on-site assessors must meet minimum requirements for training and professional qualifications. These include requirements for:

- ➢ Successfully completing a NELAP-approved basic training course and any specialized training required to assess a specific field of testing.
- ➢ Demonstrating basic qualifications pertaining to experience and education;
- ➢ Demonstrating experience pertinent to specific areas and regulations covered in an on-site assessment; and
- ➢ Certifying that the assessor has no conflict of interest that would affect performance of an assessment.

4.1 Qualifications and Training of On-site Assessment Personnel

4.1.1 Basic Qualifications

All NELAC assessors must hold a Bachelor's degree in a scientific discipline, such as chemistry, physics, biology, zoology, or botany, or in a laboratory assessment related field; or assessors may substitute equivalent education and/or experience in laboratory assessment or related fields for the education requirement. The NELAC standards also require that NELAC assessors be experienced professionals. Therefore, assessors must have experience in an environmental laboratory, either performing analyses, managing, conducting data handling and reporting, performing quality assurance, or in laboratory evaluation. All new assessors must undergo a training period in which they work side-by-side with an experienced NELAC assessor for a minimum of four assessments or until the new candidate is judged proficient by the accrediting authority. Assessors employed by accrediting authorities on the date the accrediting authority is granted NELAP recognition are exempt from on-the-job training with an experienced assessor provided they have previously conducted at least four on-site assessments and have been judged proficient by the accrediting authority.

Section 3.2.3 of the NELAC standards further requires that assessors must:

- Be familiar with the relevant Federal and state regulations, NELAC accreditation procedures and NELAC accreditation requirements;
- Have a thorough knowledge of techniques and procedures for evaluating laboratory performance, on-site assessment checklists, this manual, and other applicable technical documents;
- Be thoroughly familiar with required laboratory records;
- Be cognizant of laboratory data collection, reduction, analysis, and reporting techniques and requirements;
- Have a current working knowledge of the analytical methods applicable to the fields of testing for which accreditation is sought; and
- Have effective oral and written communications skills.

The complete array of Federal and state regulations, accreditation requirements, analytical methods, quality control requirements, and other technical specifications for laboratory performance that is relevant to NELAC accreditation is extensive. Moreover, maintaining the level of knowledge anticipated by the standards across the entire range of fields of testing would require a high level of expertise in a broad range of scientific disciplines. Consequently, it is anticipated that most NELAC

assessors will concentrate on selected fields of testing or scientific disciplines (e.g., organic chemistry analysis of wastewater, drinking water and solid waste).

4.1.2 Conflict of Interest Certification

As specified in §3.2.4 of the NELAC standards, assessors must sign a statement, prior to each assessment, that he or she has no conflict of interest that would affect their performance of the assessment. Further information concerning conflicts of interest and the appearance of a conflict is provided in Chapter 3 of this manual. Conflict of interest certifications must be laboratory-specific and must be made both by government personnel and assessors who are employed by or work under contract to third parties conducting assessments under agreement with a NELAC accrediting authority. Any assessor who is unable to make such a certification is ineligible to conduct the subject assessment unless the laboratory being assessed agrees to accept the assessor upon disclosure of the conflict of interest situation.

4.1.3 NELAP Approved Training

Note: The On-site Assessment Committee is offering the following proposal as a starting point for discussions on the assessor training program referenced in section 3.2.1 of the NELAC standards. Two options for training have been discussed by the On-site Assessment Committee: the first option consists of a basic assessor training only, the second option consists of the basic assessor training followed by specialized technical training. At this time, the committee favors the second option but invites comments from all interested parties.

The NELAC Constitution and Bylaws, Section 3.B.5, charge the On-site Assessment Committee with establishing the training requirements of the assessors. NELAP-approved training courses may be offered by government or private organizations. This manual serves as the foundation for the NELAP-approved assessor training courses (see Exhibit 4.1 and 4.2). Successful completeion of the basic assessor training course is a prerequisite for the specialized technical training courses. After completing the basic and specialized training courses, NELAP assessors are required to complete a refresher course or equivalent every other year in order to ensure they maintain an up -to-date understanding of the NELAC standards. In order to complete each NELAP-approved course successfully, an assessor must complete the minimum required course hours, complete all written assignments and exercises required, and pass a written test at the end of the course with a score of 70% or better.

All assessors must successfully complete the required training. However, during the NELAP start-up phase, assessors shall have five years to complete the basic training and any specialized training required for a field of testing from the time the first accrediting authority is granted recognition.

Specialized technical training courses are intense courses taught by experienced analysts and assessors from various government, commercial and industry laboratory programs. The course

emphasis will be on method requirements and the generation of quality, scientifically valid data. These courses shall have hands-on training in analytical software, instrumentation and review techniques for analytical data. These technical courses will help to provide assurance that assessors have the technical capabilities to evaluate the various types of laboratories and fields of testing covered by NELAC. The technical training will also serve to provide more consistency across the nation in laboratory on-site assessments. There may already be specialized technical training on the market which meets the course outlines proposed.

Most specialized technical training courses will be 2 ½ day courses which will allow an assessor to attend 2 consecutive training courses during the same week (see Exhibit 4.2) thus saving time and money. For example, during the first half of the week an assessor could attend the inorganic -metals course. Upon completion of the course at noon on Wednesday, the assessor could attend the inorganic-nonmetals course. This would allow the assessor to be certified in all aspects of inorganic chemistry.

Exhibit 4-1
NELAP Assessor
Basic Training Course

DAY 1

-NELAP overview (Chapter 1 NELAC Standards).
-Accrediting Authority (Chapter 6)
-Accreditation Process (Chapter 4)
-Proficiency Testing (Chapter 2)

DAY 2

-On-site Assessment (Chapter 3)

DAY 3

-Quality Systems (Chapter 5)

DAY 4

-Written test (am only)

EXHIBIT 4-2
NELAP Assessor
Technical Training Courses

COURSES

1. Microbiology (2.5 days)
   -Bacti
   -Viral/Parasites
   -Microscopic Particulate Analysis (MPA)

2. Inorganic- Nonmetals/Misc (2.5 days)
   -Spectrophotometric
   -IR
   -Colorimetric
   -IC
   -TOC/TOX
   -Residue/Solids
   -COD/BOD

3. Inorganic -Metals (2.5 days)
   -FAA
   -GFAA
   -ICP
   -ICP/MS
   -Sample Preparation (Digestion/TCLP/etc)

4. Organics (5 days)
   -Sample preparation
   -HPLC
   -GC
   -GC/MS
   -Instrument Software

5. Asbestos(2.5 days)
   -Bulk
   -Air
   -Water/TEM (Day 1. Assessors not requiring TEM could begin course on second day)

6. Radiochemistry (2.5 days)
   -To Be Determined

As provided in the standards (Section 2.3.1):

> "...accrediting authorities, or other entities may petition the NELAP for approval of various formal training programs which meet the NELAC standards."

Information concerning organizations currently approved to provide NELAC on-site assessor training is provided on the NELAC electronic bulletin board/Internet site at: http://134.67.104/html/nelac/ nelac.htm#NL02, or by contacting the NELAC Executive Secretary, whose name and address may also be found on the NELAC bulletin board.

4.2 Types of On-Site Assessments

4.2.1 Routine and Non-routine Assessments

The NELAC standards provide for conducting on-site assessments on a routine or non-routine basis. Each laboratory accredited must receive an on-site assessment as part of its initial application process (prior to being granted accreditation for the first time) and once every two years afterward. These routine on-site assessments are the minimum that must be conducted for all accredited laboratories, as required by the standards. They should be planned and scheduled well in advance and all parties involved will likely be given ample time to prepare for them.

Non-routine on-site assessments may be conducted, for cause, at any time, at the discretion of the accrediting authority. In general, non-routine on-site assessments may be needed in the following circumstances:

- Where the results of a previous assessment, proficiency test, or other event has identified an actual or potential performance problem;
- Where a change in the laboratory is deemed significant enough to warrant an on-site assessment for purposes of verifying that the change has had no adverse impact on laboratory performance; and/or,
- Where complaints about the laboratory have been received. In cases where the accrediting authority has documented an actual or potential performance problem at the laboratory, a non-routine on-site assessment may be used to investigate the problem or to verify that appropriate and effective corrective action has been implemented. In most cases, non-routine assessments are conducted at the discretion of the accrediting authority. Section 3.3.2 of the standards identifies one exception, however: in cases where an on-site assessment has identified deficiencies severe enough to warrant a change in the laboratory's accreditation status, a follow-up assessment should be completed (through the final report) within 45 days following completion of the assessment in which the deficiencies

were documented.

Section 4.1.8, paragraph (f), states:

For a change in key analytical laboratory personnel for which educational, training, or experience requirements exist, the State or accrediting authority must be notified within 30 calendar days when such a change occurs.

Consequently, accrediting authorities should receive notification of all significant changes in key laboratory personnel and, based on the circumstances and the information provided, may elect to conduct a non-routine on-site assessment to verify that the change has not adversely affected laboratory performance.

Accrediting authorities may also become aware of changed circumstances in laboratories independent of notification provided by the laboratory. For example:

- ➢ Key personnel from one laboratory may be reported to have joined the staff of another laboratory;
- ➢ Inquiries from laboratory clients may indicate a significant change has occurred;
- ➢ A significant change in proficiency testing results may indicate a loss of capability; or
- ➢ Laboratory correspondence may indicate a laboratory has changed locations or management.

In such cases, the accrediting authority must decide whether the change that has occurred is significant and whether a non-routine on-site assessment should be made. Section 3.3.3 (Changes in Laboratory Capabilities) specifically identifies changes in laboratory personnel, equipment or location as circumstances that "... might alter or impair analytical capability and quality." It is important to note that the standards require that laboratories report only changes in key personnel and changes in ownership (which may involve a change in location or management). Accrediting authorities may conduct an on-site assessment to evaluate the effect on performance of any change which occurs at a laboratory.

4.4.2 Announced and Unannounced Assessments

Both routine and non-routine on-site assessments may be announced or unannounced. In accordance with § 3.3.4 of the standards, accrediting authorities are not required to announce any on-site assessment to the laboratory in advance. However, announced assessments have several

advantages, including:

- ➢ Laboratory officials can ensure availability of laboratory personnel during the assessment;
- ➢ Laboratory officials can be given sufficient time to locate records or other documents to be reviewed by the assessor;
- ➢ Laboratory representatives are most able to be cooperative and responsive when the assessment is scheduled in advance at a mutually acceptable time.

These advantages are most important when conducting a comprehensive assessment. Consequently, as a general rule, it is anticipated that routine on-site assessments will be announced and scheduled at a mutually acceptable time.

During an announced assessment, assessors should be aware that they are most likely viewing the laboratory under the best circumstances. Assessors are likely to see a laboratory that has been prepared especially for the assessment; staff may be rehearsed in their responses to questions; and quality assurance records or other information may have been updated, completed, or otherwise improved for purposes of the assessment.

An unannounced assessment allows the assessor to see the laboratory operating under more normal circumstances. However, accrediting authorities and assessors should recognize that the availability of staff for interviews cannot be ensured during unannounced assessments. Unannounced assessments are most useful when the scope of the assessment is limited and the assessor is likely to be on-site for only a short period of time.

4.3 Pre-Assessment Procedures

Thorough planning and preparation prior to conducting an on-site assessment ensures that the assessment will be as efficient and effective as possible. In general, planning activities will be the responsibility of the Lead Assessor assigned by the accrediting authority[1]. All members of the assessment team must be involved in planning the assessment, however, to ensure that they are all well-prepared and can function independently while at the laboratory.

Exhibit 4-3 summarizes the pre-assessment planning process, which consists of four principal steps: 1) define the assessment scope, 2) select the assessment staff,, 3) schedule the

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[1] The processes for planning and conducting an on-site assessment presented in this Manual are designed for an applicant laboratory seeking accreditation in multiple fields of testing involving analytical methods from several different disciplines. Such assessments are likely to require a team of assessors . In many cases, the scope of the application for accreditation or staffing limitations will dictate that an assessment be conducted by a single assessor. In these cases, all of the functions identified for the assessment team will be the responsibility of the Lead Assessor.

assessment, and 4) develop the assessment plan. The exhibit identifies the parties responsible for each step in the process, the information needed to complete the step, and the outcome of each step. The final outcome of pre-assessment planning is the assessment plan which identifies the assignments for all members of the assessment team; lays out a complete schedule of activities for the assessment process, including planning, logistics, and reporting; and sets target dates for all activities through finalization of the assessment report and archiving of the assessment records.

EXHIBIT 4-3
Summary of Pre-Assessment Planning Activities

STEP	RESPONSIBLE PARTIES	INFORMATION REQUIRED	OUTCOME
1. Scoping	Lead Assessor	Application for accreditation or renewal of accreditation	List of fields of testing and methods for which laboratory seeks accreditation
2. Staffing	Lead Assessor	Scope of assessment COI certifications	Assessment Team
3. Scheduling	Lead Assessor Responsible Party of Record Assessment Team	Scope of assessment Staffing plan	Agreement on dates of assessment First level schedule of events
4. Assessment plan	Assessment Team	Application for accreditation or renewal of accreditation Report from most recent on-site assessment Most recent proficiency testing results Other information specified by § 3.4.3	Team assignments Second level schedule Assessment plan

4.3.1 Define the Scope of the Assessment

For all routine assessments, the Lead Assessor should begin the planning process by creating a master file for the assessment records and obtaining a copy of the laboratory's application for accreditation or renewal of accreditation. The application should identify the fields of testing and analytical methods for which accreditation is sought. This information will allow

the Lead Assessor to obtain the appropriate checklists for conducting the on-site assessment (see Appendix A). The Lead Assessor should be careful to verify the analytical methods identified in the application and should ensure that reference copies of all methods are available to the assessment team for use throughout planning, conducting, and reporting on the assessment.

The scope of a non-routine assessment will depend on the purpose of the assessment. If it is to be comprehensive, a similar examination of the laboratory's most recent application or accreditation certificate should be made to identify the fields of testing and analytical methods for which the laboratory is certified. The scope of a non-routine assessment that is targeted to address a specific problem will be defined by the recent history of the laboratory and/or any agreements concerning corrective action that have been made.

4.3.2 Select the Assessment Team

Once the Lead Assessor has defined the scope of the assessment, a decision can be made concerning the need for additional assessors. It is recommended that assessments be conducted by at least two qualified assessors. This will ensure that a second professional opinion is available to validate conclusions and will protect assessors from unwarranted allegations of bias. In many cases, however, accrediting authorities may not have sufficient staff to assign two assessors to each laboratory; or, in the case of a small laboratory seeking accreditation for only a limited number of analyses, assigning two assessors may not be necessary.

Upon making initial staff selections, the Lead Assessor must obtain a signed Conflict of Interest (COI) certification from each assessor to be included on the team. Refer to Section 3.2.4 of the standards and Chapter 3 of this manual for additional guidance on Conflict of Interest certification and criteria for identifying an actual or potential conflict of interest. An assessor who has a real or apparent conflict of interest is ineligible to participate on the assessment team unless the laboratory accepts the assessor upon disclosure of the conflict.

4.3.3 Schedule the Assessment

For announced assessments, the Lead Assessor should contact the laboratory's designated Responsible Party of Record and identify mutually acceptable dates for the assessment. The following items should be discussed:

- ➢ The date and time at which the assessment team will arrive at the laboratory;
- ➢ The projected date and time at which the assessment team will leave the laboratory; and

During this conversation, the Lead Assessor should be prepared to identify the members of the

assessment team and discuss the scope of the assessment, as allowed by the policies of the accrediting authority. Following the conversation, the Lead Assessor should provide written verification of the agreement in the form of a letter which announces the assessment and the mutually accepted schedule.

At this point, the assessment team members should meet, either face-to-face or by teleconference, to accomplish the following:

- ➢ Ensure the availability of all assessors;
- ➢ Agree on all team member assignments for all phases of the assessment process; and
- ➢ Agree on a schedule for completing pre-assessment planning.

4.3.4 Develop the Assessment Plan

Accrediting authorities may utilize Standard Operating Procedures and/or templates for developing assessment plans. Such tools make the assessment plan development process efficient and ensure that assessments are complete and effective. At a minimum, the assessment plan should:

- ➢ Define the scope of the assessment in terms of fields of testing, analytical methods, checklists, or other terms as appropriate;
- ➢ Identify the laboratory processes to be evaluated:

  Laboratory organization and management
  Quality system
  Personnel and staffing
  Physical facility
  Equipment maintenance
  Sample handling, acceptance and tracking
  Records management
  Reporting
  Subcontracting
  Procurement of supplies and services
  Handling of customers' complaints

  and assign team members to their review according to expertise;
- ➢ Identify the analytical procedures to be evaluated and assign team members according to expertise;

- Identify the extent to which a records review will be conducted (in accordance with § 3.4.2.2 of the NELAC standards) and assign team members according to expertise;

- Identify background materials reviewed by the assessment team;

- Identify other documents that may be needed for the assessment:
  - Assessment Confidentiality Notice
  - Conflict of Interest Form
  - Assessor Credentials
  - Assessment Assignment(s)
  - Assessor Notification Letter
  - Attendance Sheets for opening and closing conference
  - Assessment Appraisal Form

- Identify documents to be requested from the laboratory;

- Define an agenda, including dates and times for all activities to be conducted during the assessment, and assign team members as appropriate;

- Schedule private meetings of the assessment team to occur during the assessment;

- Identify, to the extent possible, laboratory staff to be interviewed during the assessment and team members who will conduct the interviews.

Members of the assessment team should review the documents identified in Exhibit 4-4. At a minimum, assessors should review the laboratory application, the final report from the laboratory's most recent on-site assessment, and the laboratory's most recent proficiency testing results. While it is recommended that these documents be reviewed prior to the on-site assessment, it is permissible to review the information during the on-site assessment if necessary.

EXHIBIT 4-4

DOCUMENTS TO BE REVIEWED PRIOR TO AN ON-SITE ASSESSMENT IN ACCORDANCE WITH § 3.4.3 OF THE NELAC STANDARDS

Copies of previous assessment reports and proficiency testing results

General laboratory information such as self-assessment forms submitted by the laboratory, SOPs, and Quality Assurance Plans

Official laboratory communications with accrediting authority staff and associated records

Available documents from recipients of laboratory reports

Current program regulations and special requirements that apply to the fields of testing or analytical methods for which the laboratory seeks accreditation (e.g., security clearance requirements, radioactive exposure protocols, etc.)

Current versions of the analytical methods used by the laboratory to conduct the tests covered by the accreditation

Each member of the assessment team should be aware of the assessment plan and given an opportunity for input. At a minimum, the Laboratory's Responsible Party of Record should be informed of the agenda for the assessment and the documents or records, if any, to be produced for the assessment team.

4.3.5 Confidential Business Information (CBI) Handling

In accordance with § 3.4.5 of the NELAC standards, the Lead Assessor must notify the Laboratory's Responsible Party of Record of the right to claim that information provided to the assessment team during the assessment is Confidential Business Information (CBI). This notification must be given verbally during the opening conference and the NELAP "Assessment Confidentially Notice" and "Confidentiality Claim" forms must be provided to the Laboratory's Responsible Party. Copies of these forms are located in NELAC Standards, Chapter 3, Appendix B. During the assessment, the assessment team is not responsible for making any determinations with respect to the validity of any CBI claim. The Lead Assessor should assume the responsibilities of a document control officer for CBI claimed information. Consequently, the Lead Assessor must be trained in procedures for handling CBI. All members of the assessment

team should also be familiar with CBI requirements. All information designated as business confidential should be appropriately marked by the Laboratory's Responsible Party of Record, listed on the "Confidentiality Claim" form by the Responsible Party and handled as CBI by the Lead Assessor. Any information identified as CBI during the assessment should be securely transported back to the accrediting authority, received, and handled consistent with the NELAP CBI requirements. Additional discussion of CBI concerns during on-site assessments is presented in Chapter 3 of this manual.

4.4 Assessment Procedures

Section 3.5 of the NELAC standards specifies that all on-site assessments consist of the following elements: an opening conference, records reviews, staff interviews, and a closing conference.

4.4.1 Opening Conference

The purpose of the opening conference is to introduce the assessment team, identify key laboratory personnel, review the purpose of the assessment and the schedule of activities, understand any special requirements that the laboratory may have (e.g., requirements related to health and safety) and allow the laboratory's Responsible Party of Record or other officials to ask any questions necessary to understand the assessment process and events that will follow the assessment. During the opening conference, the Lead Assessor should discuss CBI concerns as noted in section 4.3.5 of this manual. The opening conference should also include a walk-through of the laboratory, as discussed in Chapter 2. Exhibit 4-5 identifies topics that must be addressed at the opening conference, in accordance with § 3.5.2 of the NELAC standards. It is important to note that the standards specifically state that assessors should never, under any circumstances, sign a waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an assessment in order to gain access to the laboratory.

4.4.2 Records Reviews

Records reviews may be conducted for two purposes:

- ➢ To verify the efficacy of laboratory processes; or
- ➢ To verify data recording, calculation, reduction and reporting activities.

Exhibit 4-6 shows the minimum elements of a record set to be examined during an assessment, as required by § 3.5.3 of the NELAC standards

4.4.3 Staff Interviews

Staff interviews should be scheduled and planned, in terms of topics to be covered, in advance. The Laboratory's Responsible Party of Record may be given a list of staff to be interviewed before the

Exhibit 4-5
REQUIRED TOPICS FOR THE OPENING CONFERENCE

1. Purpose of the assessment
2. Introduction of the assessment team
3 Tests that will be examined
4. Any records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documents
5. The roles and responsibilities of key managers and staff in the laboratory
6. Confidential Business Information handling procedures
7. Any special safety procedures that the laboratory may require for the protection of the assessment team while in the facility
8. The standards that will be used by the assessors in judging the compliance status of the laboratory operation
9. Confirmation of the tentative time for the closing conference
10. Presentation and discussion of the assessment appraisal form and its purpose
11. Discussion of any questions the laboratory may have about the assessment process

assessment team arrives at the laboratory or at the opening conference. This is not a requirement however, since all details of the laboratory's operation and organization may not be apparent during the pre-assessment procedures. The Lead Assessor may establish a schedule for the staff interviews, or allow the Laboratory's Responsible Party of Record to prepare a schedule based on staff availability. Additional guidance on conducting interviews is provided in Chapter 2.

4.4.4 Closing Conference

Upon completion of the assessment, the assessment team must conduct a closing conference to inform the Laboratory's Responsible Party of Record of any deficiencies identified. The closing conference should be conducted after the team has met privately to compare notes and impressions of the laboratory, identify information gaps, and the need for additional verification of information. Once the team is satisfied that all findings are supported by objective evidence, the closing conference should be held.

The closing conference should be attended by the entire assessment team, the laboratory's responsible party, and key laboratory management and/or staff. During the closing conference, the assessment team should endeavor to be as complete as possible in its identification of deficiencies. Any information or conclusions that would support enforcement actions are discussed

EXHIBIT 4-6
MINIMUM REQUIRED RECORD SET TO BE EXAMINED DURING A NELAC ON-SITE ASSESSMENT

1. Application for accreditation submitted by the laboratory
2. Previous assessment results and reports, including proficiency testing results
3. Laboratory management structure and chains of responsibility (i.e., organization chart)
4. Qualifications statements for all key staff involved in the analysis or reporting of results and records demonstrating how key staff fulfill the qualifications requirements of their positions
5. Quality assurance plan(s)
6. Standard Operating Procedures and method protocols for each parameter for which accreditation is sought
7. Maintenance and calibration records for specific equipment separate from those included in measurement records
8. Records for the preparation and calibration of stock solutions and standard reagents
9. Documentation of the origins, purities, assays, and expiration dates of primary standards, analytical reagents and standard reference materials
10. Records associated with method-specific quality control requirements
11. Records associated with the initial method validation study associated with each method for which the laboratory seeks accreditation, to be examined in detail with the historical calibration data
12. Records associated with the methods used to estimate precision and accuracy in general for specific analyses
13. Sample receipt and handling documentation
14. Proficiency testing sample receipt and handling procedures
15. Information about the proficiency testing provider(s) used by the laboratory
16. Records of any internal audits conducted or corrective actions taken by the laboratory
17. The report of the laboratory's annual management review

at the discretion of the Lead Assessor. Before adjourning, the Lead Assessor should review items that have been claimed to be CBI, review the schedule for completing the assessment report, and inform the Laboratory's Responsible Party of Record of procedures for responding to the assessment findings, which include:

- ➢ Submitting a plan of corrective action, followed by an additional on-site assessment for verification purposes, if necessary; or

- ➢ Requesting a review of the assessment in accordance with the provisions of Chapter 4 of the NELAC standards.

The closing session should reflect the fact that the purpose of the assessment is to judge the extent to which the laboratory is in compliance with the NELAC standards, not to pass judgement on the overall quality of the operation. Consequently, the closing session should always be conducted in a factual and positive manner. Laboratory officials must be given the opportunity to clarify any misunderstandings or provide additional information which may have a bearing on potential laboratory deficiencies. However, it should be recognized by on-site assessors and laboratory officials that discussions of potential deficiencies may not always lead to resolution or agreement. It is expected that assessors, laboratory officials and staff will maintain courteous and professional attitudes during the assessment.

4.4.5 Standards for Assessment

The NELAC On-site Assessment Standards specify that key areas be evaluated during the assessment. These items are listed in Exhibit 4.7. Detailed instructions for the assessment of these areas are found in Chapter 5 of this manual.

Exhibit 4-7
Areas To Be Evaluated
During On-site Assessment

1) Size, appearance, and adequacy of the laboratory facility;
2) Organization and management of the laboratory;
3) Qualifications and experience of laboratory personnel;
4) Receipt, tracking and handling of samples;
5) Listing/inventory, condition, and performance of laboratory instrumentation and equipment;
6) Source, traceability and preparation of calibration/verification standards;
7) Test methods (Including the adequacy of the laboratory's standard operating procedures as well as confirmation of the analyst's adherence to SOPs, and the analyst's proficiency with the described task);
8) Data reduction procedures, including an examination of raw data and confirmation that final reported results are derived from raw data and original observations;
9) Quality assurance/quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan;
10) General health and safety procedures as they relate to good laboratory practices; and
11) Laboratory waste disposal procedures.

4.4.6 Reporting

Although reporting actually begins during the closing conference when the Lead Assessor presents a summary of the assessment findings, the final product for the assessment is a formal, written report. Consistent with § 3.7.2 (Report format) of the NELAC standards, the final report for an on-site assessment should be written in narrative form and should describe existing conditions at the laboratory and identify and describe any deficiencies. At a minimum, the report must include:

1. Identification of the laboratory (name and address);

2. Date or dates of the assessment;

3. Identity and affiliation of each member of the assessment team;

4. A statement of the objectives of the assessment, including correction of prior deficiencies, if applicable;

5. A summary of conditions at the laboratory;

6. Documentation of the findings resulting from the assessment (including a description of all deficiencies found and a summary of the objective evidence supporting the findings); and

7. Comments and recommendations.

All deficiencies described must be described in the context of the applicable NELAC standard or appropriate test method, and the specific standard (section number and text) must be cited.

The final report must be completed and transmitted to the laboratory within 30 working days following completion of the on-site assessment. Information from the report concerning the results of the assessment and the laboratory's status must also be forwarded to NELAP for inclusion in the NELAC data base. The report deadline may be delayed in cases where the accrediting authority has cause to conduct further investigation of conditions or practices at the laboratory, or is taking another action related to the accreditation status of the laboratory. In such cases, the accrediting authority must notify the laboratory of the proposed date for completion of the report and of the cause for the delay.

All on-site assessment reports are eventually made available to the public upon request. In accordance with § 3.7.5, reports will be made available first to the responsible official(s) at the laboratory. Laboratory officials must be allowed to request clarification regarding any aspect of the report and may take exception to any findings reported by notifying the accrediting authority in writing within 15 working days following receipt of the report. Once any issues are resolved, the on-site assessment report must be finalized and transmitted to the laboratory and NELAP. Reports cannot be released to the public until they are final. In accordance with Freedom of Information laws, any information judged to be proprietary, financial and/or trade information, or relevant to an on-going enforcement investigation is exempt from public disclosure requirements.

4.4.7 Closure and Records Retention

Upon completion of the final report from each on-site assessment, the assessor or lead assessor should ensure that a complete file containing all of the original records of the assessment, is compiled and stored according to the standard procedures specified by the accrediting authority. The file should include:

- A list of any documents reviewed by the assessor(s) prior to conducting the on-site assessment (such as the application for accreditation, reports of laboratory performance on recent proficiency tests; quality system manuals, laboratory methods manuals, reports from previous on-site assessments, or any other documents). Either the location of each document should be

noted on the list or a copy of the document should be included in the file.

- Copies of correspondence between the accrediting authority and laboratory officials, and correspondence between the accrediting authority or lead assessor and members of the assessment team (including certifications concerning personal and/or organizational conflict of interest) generated prior to or following the on-site assessment.

- Written entries documenting telephone conversations with laboratory officials pertaining to the on-site assessment or corrective action following the on-site assessment.

- The original on-site assessment checklists completed during the assessment (also completed in ink).

- Any photographs (and negatives) and/or audio or video tape recordings made during the assessment.

- All copies of laboratory records made by members of the assessment team or provided by laboratory officials.

- The final version of the assessment report.

- The corrective action plan, if any, submitted by the laboratory and any related correspondence or written comments.

Files should be archived in accordance with the procedures established by the accrediting authority. In accordance with § 3.7.6 of the NELAC standards, on-site assessment files must be maintained for a period of ten years, or longer if required by state statute or Federal regulation.